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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,487	10/29/2003	Durward I. Faries JR.	1322.0063CNT	5214

27896 7590 01/26/2007  
EDELL, SHAPIRO & FINNAN, LLC  
1901 RESEARCH BOULEVARD  
SUITE 400  
ROCKVILLE, MD 20850

EXAMINER
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PELHAM, JOSEPH MOORE

ART UNIT	PAPER NUMBER
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3742

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/695,487

Applicant(s)

FARIES ET AL.

Examiner

Joseph M. Pelham

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 70-115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/23/05, 5/17/05, 7/6/04.</u>                                | 6) <input type="checkbox"/> Other: ____.                          |

***Claim Rejections - 35 USC § 112***

Claims 70-115 are rejected under 35 U.S.C. 112, *first paragraph*, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent claims 70, 81, 89, 97, 106, and 112 all recite "medical items [that] *include* a particular temperature range for utilization and a prescribed time interval for thermal treatment" (Examiner's emphasis). The manner in which this information is "included" with the medical item is not discussed in the specification, *nor in any of the related patents incorporated by reference*. Applicant is urged to be mindful of new matter. It is not clear that the continuity of the instant application is correctly stated.

Claims 70, 82, 90, 97, and 107 all recite a "monitor unit to control thermal treatment... and to *monitor... temperature and... residence time of [a] medical item for compliance with [a] particular temperature range and... thermal treatment time interval* (Examiner's emphasis). The specification does not discuss such monitoring for the purpose of compliance with a temperature range and treatment time interval, *nor do any of the related patents incorporated by reference*.

Claims 88 and 112 recite "indicating to a user prior thermal treatment of [a] medical item." A discussion of temperature and residence time indicating prior treatment is absent from the instant specification, and the *related patents incorporated by reference*.

Claims 70-115 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As discussed above, independent claims 70, 81, 89, 97, 106, and 112 all recite "medical items [that] include a particular temperature range... and a prescribed time interval" (Examiner's emphasis). The disclosure provides no indication of how this information is "included," rendering the claims indefinite.

***Claim Rejections - 35 USC § 102***

Claims 97-112 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. 4923681.

Referring to Fig. 1 and col. 5, lines 53-64, and considering use of the device by an attendant communicating with a superior, a doctor for example, US'681 discloses the device as claimed, including thermal treatment of medical items whose treatment temperature and time requirements are known by the artisan, user entry of temperature and time, display of both, notice of exceeding utilization temperature or treatment time being the visible indication of these values to the attendant, indicating removal time by timer reading, and ending treatment when compliance with the known treatment regime is ended. The attendant who places the medical item in the treatment device will feel an

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elevated temperature in an item to be treated if it has been previously treated, hence he/she register will this information and transmit same to the user.

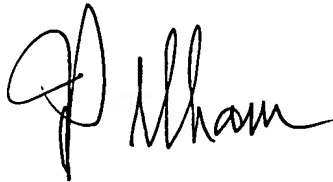
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Pelham whose telephone number is 571-272-4786. The examiner can normally be reached on M-F 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on 571-272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1/19/07



JOSEPH PELHAM  
PRIMARY EXAMINER